UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

NEIL STRONG, Plaintiff, vs. STRYKER CORPORATION, a Michigan corporation; and STRYKER SALES CORPORATION, a Michigan corporation, Defendants.	Court File No. ________________ **COMPLAINT** **AND DEMAND FOR JURY TRIAL**

Plaintiff, for his Complaint against Defendants, states and alleges as follows:

JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. § 1332.

2. This Court has personal jurisdiction over Defendants pursuant to M.S.A. § 543.19, in that, at all relevant times described herein, Defendants: (a) transacted business in the state of Minnesota; and/or (b) committed acts in Minnesota causing injury. Defendants are corporations maintaining sufficient minimum contacts with this judicial district to subject the corporations to personal jurisdiction here.

3. The amount in controversy in this matter exceeds $75,000, exclusive of interest and costs.

PARTIES

4. Plaintiff Neil Strong is a citizen of the state of California. Plaintiff Neil Strong underwent right shoulder surgeries on October 10, 2001, March 9, 2004, and March 21, 2005. After each surgery, Plaintiff Neil Strong was treated post-operatively with a Pain Pump designed, developed, manufactured, assembled, packaged, promoted, distributed and/or sold by Defendants Stryker Corporation and Stryker Sales Corporation.

5. Defendants Stryker Corporation and Stryker Sales Corporation are Michigan corporations with their principal places of business in Kalamazoo, Michigan. Stryker Sales Corporation is a subsidiary of Stryker Corporation and is registered to do business in the state of Minnesota. Stryker Corporation and Stryker Sales Corporation have in fact conducted regular and sustained business in Minnesota by selling and distributing their products in Minnesota, as described below.

FACTUAL ALLEGATIONS

The Product

6. At all relevant times described herein, Defendants designed, manufactured, assembled, packaged, promoted, marketed, distributed and/or sold a product or device referred to as a Pain Pump.

7. Defendants' Pain Pump is a medical device designed to deliver a continuous and rate-controlled amount of pain medication, via catheter, directly to a surgical site, including the joint space, immediately following surgery, for post-surgical pain management over the course of several days.

8. The Pain Pump is designed and intended to be used with commonly used anesthetics, such as lidocaine, marcaine, or sensorcaine with or without epinephrine, over the course of two days or more.

9. At all pertinent times, Defendants represented to the public and to healthcare professionals that the Pain Pump was a safe and effective pain management product and that the Pain Pump could appropriately be used for orthopedic surgery or use in or near the shoulder joint.

10. In fact, the Pain Pump is not a safe and effective pain management product and was neither approved nor approp0riate for use in orthopedic surgery or in or near the shoulder joint, in that the continuous injection of anesthetics, with or without epinephrine, over the course of two or more days directly into or near the shoulder joint, as achieved by the Pain Pump, can destroy the chondrocytes, the articular cartilage cells in the shoulder joint, such that the shoulder joint cartilage suffers progressive, global degeneration. Global destruction of shoulder joint cartilage is known as chondrolysis, a painful, disabling, and irreversible condition.

Plaintiff's Injury

11. In April 2001, Plaintiff, 16-year-old Neil Strong, injured his right shoulder while throwing a baseball. Plaintiff underwent conservative treatment, including physical therapy.

12. When conservative treatment failed, Plaintiff, his parents, his surgeon, Dr. Laith Farjo, and Dr. Farjo's assistant had several discussions regarding the risks and benefits of surgical treatment, including the risks of failure to improve symptoms, loss of

motion, infection, neurovascular injury and recurrent symptoms. Of course, because Defendants had never warned Dr. Farjo of the risk of permanent, total destruction of Plaintiff's shoulder by the Pain Pump's continuous infusion of anesthetic medication over several days, Plaintiff and Dr. Farjo did not discuss this most serious risk. Plaintiff, his parents, and Dr. Farjo agreed that surgery was warranted.

13. On or about October 10, 2001, Dr. Farjo performed an arthroscopic Bankart repair on Plaintiff's right shoulder, a procedure performed in and around the joint space.

14. At the conclusion of the surgery, a Stryker Pain Pump catheter was placed in the operative site, that is, in the shoulder joint space, and was connected to Defendants' Pain Pump filled with anesthetic medication.

15. Defendants' sales representatives had represented to Dr. Farjo that the Pain Pump could be safely used in any operative site, including the shoulder joint space, and Dr. Farjo placed the Pain Pump catheter in Plaintiff's joint space in reliance on this representation.

16. Plaintiff Neil Strong was instructed to and did remove the Pain Pump approximately three days after his surgery.

17. Following surgery, Plaintiff Neil Strong began to experience significant degenerative changes in his shoulder joint.

18. Plaintiff was a high school baseball player and had hoped to obtain a college baseball scholarship, but Dr. James Telfer, who was also treating Plaintiff, informed Plaintiff in October 2002 that because of this degeneration, Plaintiff would not likely be returning to baseball.

19. On or about March 9, 2004, Plaintiff Neil Strong underwent a second right shoulder surgery by Dr. Laith Farjo, which revealed that his articular cartilage had suffered significant degeneration since his first surgery. A second Stryker Pain Pump catheter was placed in Plaintiff Neil Strong's joint space following this procedure, which was removed approximately three days later.

20. Plaintiff's shoulder only continued to get worse. On or about March 21, 2005, Plaintiff underwent a third right shoulder surgery, this time by Dr. Telfer. Dr. Telfer observed that Plaintiff's articular cartilage had suffered extensive degeneration. Dr. Telfer, who also had not been warned of the possibility of cartilage damage by Defendants, placed a Stryker Pain Pump catheter in the shoulder joint space, which was removed approximately three days later.

21. After this surgery, Dr. Telfer informed Plaintiff that he "[did] not have good options for the shoulder," so Dr. Telfer referred Plaintiff to Dr. Joseph Iannotti in Cleveland, Ohio. Dr. Iannotti observed the extensive degeneration and opined that no surgical intervention would provide relief from Plaintiff's symptoms, but that these symptoms would increase over time.

22. Plaintiff's symptoms did worsen over time, and Plaintiff ultimately sought the opinion of Dr. Brian Cole in Chicago, IL. On or about June 25, 2008, Plaintiff underwent a fourth right shoulder surgery, performed by Dr. Cole, who observed that Plaintiff "had three previous intraarticular procedures all with pain pumps placed postoperatively," and that the articular surface was "complete[ly] denuded of articular cartilage down to subchondral bone."

23. In October 2009, Plaintiff Neil Strong's treating physician, Dr. Christopher Behr, noted that Plaintiff "does have chondrolysis of the shoulder from prior surgery."

24. The Pain Pumps used immediately after Plaintiff Neil Strong's surgeries in October 2001, March 2004, and March 2005 subsequently caused the degeneration of the cartilage in his shoulder.

25. The administration of anesthetic solution by the Pain Pumps directly led to cartilage and tissue damage in Plaintiff's shoulder, resulting in severe pain, weakness, and decreased range of motion, and Plaintiff's shoulder requires and will continue to require further medical treatment, including a total shoulder replacement.

26. Plaintiff Neil Strong's injuries have resulted in permanent disability in his right shoulder and limited daily activity.

27. As a direct result of the use of Defendants' Pain Pump, Plaintiff Neil Strong has suffered harms and losses, including, but not limited to, severe physical pain, mental suffering, inconvenience, loss of the enjoyment of life, past and future medical, surgical, and related expenses, past lost wages, loss of earning capacity, loss of household services, and care gratuitously rendered.

Defendants' Misconduct

28. Defendants misled the medical community, and the general public, by making false representations about the safety of their Pain Pump. Defendants failed to take necessary and required pre-marketing steps to ensure that their Pain Pump was safe before selling it to orthopedic surgeons for use in shoulder joints. As Defendants gained knowledge of the danger of using Pain Pumps in the joint space, Defendants understated,

disregarded, and/or concealed that knowledge, all to the detriment of patients like Plaintiff Neil Strong.

29. At all pertinent times, Defendants knew or should have known that their Pain Pump could cause chondrolysis.

30. Defendants knew that their Pain Pump was never cleared by the United States Food and Drug Administration (FDA) for use in or near the joint space, or even for use in orthopedic surgery at all.

31. In fact, Defendants knew or should have known that starting in the late 1990's, the FDA had repeatedly *rejected* 510(k) requests by pain pump manufacturers, including Defendants, for permission to market pain pumps for orthopedic use and/or use in the joint space, because of a lack of safety data.

32. Without 510(k) approval, the only option available to Defendants to obtain FDA permission to legally market their Pain Pumps for orthopedic and joint space use was through a separate Pre-market Approval (PMA) process, which required Defendants to conduct safety testing and report safety information to the FDA. Rather than going through the PMA process, however, Defendants simply ignored the FDA safety requirements altogether, and marketed Pain Pumps for the very use for which the FDA had denied them permission.

33. Although Defendants actually and consciously considered whether joint space use of Pain Pumps would be safe, Defendants never conducted a single study to determine the safety of using their Pain Pumps in the shoulder joint.

34. Had Defendants submitted to the PMA process and conducted appropriate safety studies back in the 1990's, as they were obligated to do after the FDA's denials of 510(k) applications relative to joint space pain pump use, Defendants would have determined that continuous infusion of anesthetics into the joint space via pain pump could cause chondrolysis.

35. Defendants failed to test the Pain Pump for safety even though Defendants' own functional specifications for their Pain Pumps listed "medical toxicity" as a "potential company risk" which deserved "more investigation in terms of all possible drugs intended to [be] use[d] and their indications for use."

36. Had Plaintiff's surgeons, Dr. Farjo and Dr. Telfer, known that Defendants' Pain Pumps were not FDA-approved for orthopedic and joint space applications, and that Defendants had not performed any safety testing for joint space use of Pain Pumps, they would not have used Defendants' Pain Pumps in Plaintiff's shoulder following the surgeries.

37. Defendants never conducted a reasonable search of the available medical literature to determine whether commonly used anesthetics were toxic to articular cartilage.

38. Had Defendants performed such a literature search, they would have found medical literature from as early as the 1930's discussing the toxicity of anesthetics to articular cartilage.

39. In April 2000, some 18 months before Plaintiff's first right shoulder surgery involving the Pain Pump, a drug manufacturer sent Defendants a package insert for the

drug manufacturer's local anesthetics, which showed that the local anesthetics were not approved by the FDA for infusion into the joint space. Defendants nevertheless did nothing to investigate the safety of continuously infusing local anesthetics into the joint space via Pain Pump, but rather continued to promote Pain Pumps for continuous infusion of local anesthetics into the joint space.

40. In July 2000, more than a year before Plaintiff's first right shoulder surgery involving the Pain Pump, Defendants learned that another drug manufacturer, who met with Defendants about the possibility of combining the drug manufacturer's drugs with Defendants' Pain Pumps, did not have permission from the FDA to market its anesthetics for use in the joint space. Defendants again declined to perform any safety testing for continuous infusion of anesthetics into the joint space.

41. One year before Plaintiff's first right shoulder surgery involving a Stryker Pain Pump, Defendants received feedback from orthopedic surgeons participating in a customer preference trial regarding Pain Pumps, who noted concerns about toxicity. Defendants did nothing in response to these concerns, except to continue marketing the Pain Pump for joint space use.

42. Two years before Plaintiff's second right shoulder surgery involving a Stryker Pain Pump, a medical journal published an article expressing concerns that the performance of post-operative pain pumps, which could infuse potentially toxic medications, had not been independently investigated. Defendants still declined to perform any safety testing and still continued to market their Pain Pumps for orthopedic and joint space use.

43. In 2004, another article was published in a peer-reviewed medical journal discussing chondrolysis and noting that pain pumps were used in surgeries that resulted in chondrolysis. Defendants still took no steps to investigate the safety of their Pain Pumps in this unapproved and untested use.

44. Several weeks before Plaintiff's third right shoulder surgery involving a Stryker Pain Pump, Defendants' own paid medical consultant, Dr. Lonnie Paulos, informed Defendants that cases of chondrolysis attributable to Pain Pumps had arisen. Dr. Paulos advised Defendants to "cover it's [sic] butt" by changing the labeling on the Pain Pumps and performing a study to test the safety of its Pain Pumps when used in the joint. Defendants did neither of these things, but instead continued to market the Pain Pump to orthopedic surgeons for use in the joint space.

45. Defendants did nothing to investigate these cases identified by Dr. Paulos and failed to promptly enter them into Defendants' internal complaint system.

46. In December 2005, another prominent orthopedic surgeon, Dr. Charles Beck, informed Defendants that their Pain Pumps were causing chondrolysis, and provided Defendants with a draft of his paper on the subject, which he presented in summer 2005 and summer 2006 in national meetings of orthopedic surgeons, and which was published in a peer-reviewed medical journal in 2007. Again, Defendants chose to do nothing to determine the safety of their Pain Pumps in the joint space.

47. In the ensuing months and years, more peer-reviewed medical journal articles were published linking pain pumps to chondrolysis, and that library continues to grow. Defendants ignored these as well, instead maintaining that there was insufficient evidence

that joint space use of Pain Pumps caused chondrolysis. Defendants continued to market their Pain Pumps to orthopedic surgeons for joint space use.

48. On November 13, 2009, the FDA issued a report warning healthcare professionals "to not use [pain pumps] for continuous intra-articular infusion of local anesthetics after orthopedic surgery," the very use for which Defendants encouraged Plaintiff Neil Strong's surgeons to use the three Pain Pumps in Plaintiff's shoulder.

49. In the same report, the FDA stated that it "has not cleared any [pain pumps] with an indication for use in intra-articular infusion of local anesthetics," a fact of which Defendants were well aware back in the late 1990's, but which Defendants ignored and failed to communicate to Plaintiff Neil Strong, his surgeons, or anyone else.

50. To this day, and in the face of a growing body of medical literature to the contrary, Defendants maintain that their Pain Pumps do not cause chondrolysis.

51. At all pertinent times, and despite their knowledge that the Pain Pump could cause chondrolysis, Defendants nevertheless marketed their Pain Pumps to orthopedic surgeons for orthopedic use, including joint space use.

52. Defendants' sales representatives were often present in the operating room when an orthopedic surgeon was placing the Pain Pump, and Defendants trained their sales representatives to instruct the surgeon on Pain Pump catheter placement in the joint, the very untested and dangerous use for which Defendants and other pain pump manufacturers had been denied FDA approval and had performed no safety testing.

53. Defendants' own medical consultant has testified that Defendants' sales reps approach doctors in the operating room and encourage them to use Pain Pumps in the shoulder joint.

54. At some time prior to 2001, Defendants produced a spreadsheet used to train sales representatives on how the Pain Pump was to be used in various surgeries. The spreadsheet listed the shoulder joint space as a proper area for catheter placement.

55. At no time did Defendants ever provide an adequate, meaningful warning to orthopedic surgeons, or anyone else, against using the Pain Pump in orthopedic surgeries or in or near the joint space.

56. In November 2006, Defendants drafted a form letter to doctors, noting that their pain pumps "are not indicated for intra-articular delivery." Unfortunately, this letter:

(a) Did not mention the FDA's explicit denial of permission to market Pain Pumps for joint space use some eight year prior to this letter;

(b) Did not mention that Defendants had performed no safety testing to determine whether joint space use was safe;

(c) Was not sent to all of Defendants' customers, but only to those doctors who contacted Defendants requesting it; and

(d) Quite possibly was never sent to anyone, since the Stryker personnel tasked with sending the letters cannot recall whether they ever sent any letters out.

57. In October 2007, after receiving numerous complaints about chondrolysis caused by its Pain Pumps, Defendants changed their product package insert (or product

"label") to note that some animal and in-vitro studies "suggested a relationship between local anesthetics and chondrocyte toxicity; however, clinical studies to date have not shown this related toxicity." This label change failed to provide surgeons with an adequate warning because it:

(a) Failed to reveal that it was *continuous infusion* of local anesthetics *via Pain Pump*, not simply "local anesthetics," that had been shown by animal and in-vitro studies to be toxic to articular cartilage;

(b) Failed to make reference to the substantial and growing body of studies that had made a causal connection between Pain Pumps and chondrolysis;

(c) Failed to acknowledge that clinical studies would not be ethically permitted by the FDA precisely because the danger of joint space use of Pain Pumps was established in the medical literature; and

(d) Failed to take any steps to bring this label change to the attention of its customers, the orthopedic surgeons, by either a dear doctor letter or by instructing sales representatives to advise doctors of the change; orthopedic surgeons seldom saw the label after their first introduction to the product, since the Pain Pump was generally unpacked by surgical staff outside the sterile field.

58. Defendants made a similarly meaningless label change in May 2008, which, like the 2007 label change, likely never reached the surgeon.

59. The inadequacy of both of these label changes was corroborated on February 16, 2010, when the FDA updated the advisory report regarding pain pumps and chondrolysis and stated that the "significance of this injury to otherwise healthy young

adults warrants notification to health care professionals," and that "the FDA is requiring the manufacturers of local anesthetics and of pumps that may be used to infuse local anesthetics to update their product labels to warn healthcare professionals about this potential serious adverse effect."

60. At no time did Defendants ever:

(a) Perform or commission any testing to determine the safety of the Pain Pump when used in the joint space;

(b) Warn surgeons that Defendants had performed no safety testing;

(c) Warn surgeons that Defendants, their predecessor in pain pumps, and other pain pump manufacturers, had been specifically denied FDA approval to market the Pain Pump for joint space use;

(d) Instruct its sales force to warn surgeons that the safety of the Pain Pumps when used in the joint had not been tested or established, and that the FDA had expressly denied approval for this specific use; or

(e) Send out a "Dear Doctor" letter or other meaningful and candid warning to surgeons that joint space use of Pain Pumps was unsafe.

STATUTE OF LIMITATIONS AND FRAUDULENT CONCEALMENT

61. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts by Defendants, as alleged herein.

62. Plaintiff and his physicians were kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiff could not reasonably have known or become aware of the dangerous nature of

and the unreasonable adverse side effects associated with, nor establish any provable compensable damages caused by, the joint space use of Defendants' Pain Pumps as a result of this concealment.

63. Because of Defendants' refusal to conduct appropriate studies to determine the safety of anesthetics on cartilage, and because of their failure to apprise physicians of information they held secretive within their companies, Plaintiff was deprived of evidence of a causal connection between his injury and Defendants' Pain Pumps and their negligent acts and omissions.

64. Defendants are and were under a continuing duty to disclose the true character, quality, and nature of their Pain Pumps. Because of Defendants' concealment of the true character, quality and nature of their Pain Pumps, Defendants are estopped from relying on any statute of limitations defense.

65. Defendants knew that their Pain Pumps were not approved for use in joints, and that their Pain Pumps were being used in the joint.

66. Defendants attempted to gain FDA approval for use of their Pain Pump in the joint space on March 28, 2001. At that time, Defendants indicated that they knew that the FDA had required the original manufacturer of the predicate device for their Pain Pump to remove such an indication from its label.

67. On June 5, 2001, FDA approved Defendants' Pain Pump for use in general surgery, but specifically and deliberately omitted Defendants' requested indication for use in the joint space.

68. Despite this specific, affirmative denial, Defendants fully intended to and did market their Pain Pumps to orthopedic surgeons, including Plaintiff's surgeons, Dr. Farjo and Dr. Telfer, for use in the joint space.

69. As indicated in the deposition testimony of Dr. Lonnie Paulos, Defendants fraudulently concealed the dangerous nature of their Pain Pumps by affirmatively telling orthopedic surgeons that Pain Pumps could be used in the intra-articular joint space.

70. When Defendants learned in July 2000 that local anesthetics were not approved for injection into the joint space, Defendants fraudulently concealed this fact from consumers and the medical community when they marketed their Pain Pumps to orthopedic surgeons for continuous infusion of local anesthetics into the joint space.

71. Defendants continued to unlawfully market their Pain Pumps even after customer preference trials indicated in October 2000 that surgeons were concerned about toxicity.

72. Defendants fraudulently concealed the dangerous nature of their Pain Pumps by withholding the information regarding FDA's denial of the orthopedic or joint space indications from their sales representatives, research and development personnel, operations management personnel, regulatory quality personnel, plant management personnel, engineering personnel, marketing personnel and product management personnel. For example, in 2001, Danielle Lopez, a Stryker marketing associate, retyped a spreadsheet she received upon taking her position that indicated the glenohumeral joint space as an area for catheter placement. She then used that spreadsheet during sales trainings to illustrate how to use the pain pump in various surgeries. Defendants withheld

this information knowing that their Pain Pumps were being designed and marketed for use in the joint space.

73. Defendants' marketing product manager knew that doctors were using the Pain Pumps in the joint space in 2003 and 2004, and at least some of Defendants' regulatory personnel knew that this was not a cleared indication for use.

74. On November 3, 2005, in an attempt to conceal the dangerous nature of their Pain Pumps from consumers and the medical community, Defendants provided false and misleading information to the FDA in response to the FDA's request for information about chondrolysis. Jennifer Hoffman, Stryker's Regulatory Affairs Representative, misrepresented that there had only been 7 reported events of chondrolysis associated with use of Pain Pumps when in fact, Ms. Hoffman and Defendants had known since February 2005 of as many as 30 events of chondrolysis associated with the use of pain pumps. For example,

(a) In 2003, Stryker sales representative and later sales manager, Don Kelly, was informed by a physician and Stryker consultant, Dr. Lonnie Paulos, of injury to a patient's joint that was associated with the patient's use of a pain pump.

(b) On August 11, 2005, Dr. Charles Beck notified Stryker of 13 patients with post shoulder surgery chondrolysis with Defendants' Pain Pumps.

(c) On February 11, 2005, Dr. Paulos informed Brady Shirley, Vice President of Sales, of additional cases of chondrolysis and warned that Stryker should consider changing its label.

(d) On February 15, 2005, Dr. Paulos informed Stryker that he knew of at least 30 cases of chondrolysis associated with the use of Pain Pumps.

75. Defendants fraudulently concealed the dangerous nature of their Pain Pumps from consumers and the medical community when Steven Docsa, Stryker's Clinical Monitor, affirmatively stated on March 3, 2005, that Stryker should do nothing in response to physician reports of chondrolysis and Dr. Paulos's suggestion that Defendants undertake an animal study to test the safety of their Pain Pumps on cartilage. Docsa took this position despite the suggestion by other personnel, including Jennifer Hoffman, that the complaints should be entered into Defendants' quality assurance system, SuPER, and despite Defendants' policies and procedures, which required that complaints, even if they did not meet FDA's reporting requirements, should be entered into SuPER.

76. Defendants' policies and procedures, and federal law, required Defendants to follow-up and investigate the injuries reported by Dr. Paulos, including getting specific information, including dates of events, the specific injury, how the product was being used, how the patient was doing, and if follow-up treatment was needed. However, Defendants failed to respond to Dr. Paulos's communications, much less investigate the injuries he reported.

77. Defendants attempted to further conceal the dangerous nature of their Pain Pumps when, on January 19, 2006, Ms. Hoffman contacted Dr. Beck regarding a study Dr. Beck was publishing regarding the association between pain pumps and chondrolysis. Ms. Hoffman asked Dr. Beck if he could emphasize that pain pumps were not the cause

of chondrolysis. Ms. Hoffman's intent, as documented affirmatively in the communication to Dr. Beck, was to deflect the cause of chondrolysis from Defendants' Pain Pump. Dr. Beck responded that his professional opinion was that it was the combination of volume, pressure, and medication achieved by the Pain Pump that was implicated.

78. Defendants fraudulently concealed the dangerous nature of their Pain Pumps in October 2006, when Defendants' sales managers failed to provide information to Defendants' sales reps that was contained within a document circulated by Stryker personnel who attended two medical conventions discussing the association between chondrolysis and Pain Pumps. The document, or "hot sheet," noted that Pain Pumps were indicated for infusion only through particular routes, not including the joint space, and advised readers to discuss this information with customers. Defendants' sales managers never distributed the information to Defendants' sales reps.

79. In November 2006, Defendants prepared a form letter to doctors regarding chondrolysis; however, the letter mischaracterized the dangers of the Pain Pump when used in the joint space by indicating that no clinical studies directly linked the Pain Pumps to chondrolysis. The letter failed to state that the FDA, because of safety concerns, never would have approved such a study, as there was already extant literature suggesting that such use was unsafe. The letter also mischaracterized Defendants' Pain Pumps by stating that the Pain Pumps were not indicated for joint space delivery without stating that such use had been specifically denied by the FDA. Finally, Defendants did not send the letter out to physicians unless a physician requested it. In fact, the Stryker

employees tasked with sending the letters out cannot recall whether any letters actually were sent out.

80. In December 2006, Defendants held a training for new sales reps, in which Defendants did not inform the new reps that Pain Pumps were not cleared for use in the joint space, despite the fact that Defendants knew that its representatives were present in the operating rooms, prepared the Pain Pumps for the surgeons, and instructed the surgeon on how to use the Pain Pumps.

81. In October 2007, Defendants fraudulently concealed the dangerous nature of their Pain Pumps by indicating on the Pain Pump package insert that animal and in vitro studies suggested a relationship between local anesthetics and chondrocyte toxicity, but then proceeded to undermine that information by stating that no clinical studies have shown such toxicity. Further, Defendants did not recall any of its existing labels.

COUNT I – STRICT PRODUCTS LIABILITY – DESIGN DEFECT

82. Plaintiff incorporates by reference the preceding allegations as if fully set forth herein.

83. Defendants are engaged in the business of selling Pain Pumps, and they designed, manufactured, assembled, labeled, marketed, distributed, and/or sold the Pain Pumps used in Plaintiff Neil Strong's right shoulder.

84. Plaintiff Neil Strong is in the class of persons that Defendants should reasonably foresee as being subject to the harm caused by a defectively designed Pain Pump because Plaintiff Neil Strong was the type of person for whom the Pain Pump was intended to be used, that is, he was an orthopedic shoulder surgery patient.

85. Defendants designed, intended, marketed and promoted their Pain Pumps for use in orthopedic surgery and/or for use in or near the joint space.

86. Defendants placed into the stream of commerce Pain Pumps that were defective and in an unreasonably dangerous condition such that the foreseeable risks, including the risk of permanent destruction of the shoulder joint, exceeded the benefits associated with the design and/or formulation of the Pain Pump.

87. The Pain Pumps used after Neil Strong's surgeries were defective, unsafe, not reasonably fit, and unreasonably dangerous for their intended use, that is, use in the shoulder joint, in that, among other things:

(a) Defendants failed to perform or report on any testing to determine the safety of orthopedic and/or joint space use of the Pain Pump; and

(b) The continuous feed of post-surgical anesthetic solutions at the delivery rate used by the Pain Pump can and did cause toxic destruction of the chondrocytes, resulting in global destruction of Plaintiff Neil Strong's articular shoulder cartilage.

88. These defects caused Plaintiff Neil Strong's injuries and damages.

89. These defects in the Pain Pumps existed when they left the Defendants' supervision and control.

90. The Pain Pumps were expected to and did reach the ultimate user without substantial change in the condition in which they were sold and distributed.

91. Alternative pain management methods, including alternative designs of Defendants' Pain Pumps, were reasonably available, practicable and would have eliminated the risk of chondrolysis. These alternatives included, but are not limited to:

(a) Administration of oral pain medications; and

(b) Pain Pumps designed, intended, and marketed to be used in FDA-approved pain management indications, such as intravenous, intra-arterial, or subcutaneous infusion, including nerve block protocols.

92. The risks of using the Pain Pump in or near the shoulder joint space, including destruction of the shoulder joint, rendered any therapeutic benefits of the Pain Pump worthless and of no value. That is, any pain relief to Plaintiff's shoulder joint provided by the Pain Pump was worthless because the same Pain Pump was also the cause of the complete destruction of the same shoulder joint.

93. Defendants' failure to perform any testing to determine the safety of joint space use of their Pain Pumps, as well as Defendants' consequent failure to consider alternatives to such use of their Pain Pumps, rendered their Pain Pumps unreasonably dangerous for use in the shoulder joint.

94. Testing to determine the safety of joint space use of Defendants' Pain Pumps would have revealed to Defendants, as it has revealed and continues to reveal to researchers in the orthopedic community, that continuous infusion of anesthetic medication into the shoulder joint over the course of two days or more can cause chondrolysis, a serious injury which would have been foreseeable to Defendants had

Defendants performed such testing before Defendants began distributing their Pain Pumps to be used in the shoulder joint.

95. The dangers posed by the defective condition of the Pain Pump, particularly that the Pain Pump's delivery of anesthetic solution into or near the shoulder joint space would cause destruction of the shoulder joint, were not readily recognizable by the ordinary users of the Pain Pump.

96. The Defendants knew, or reasonably should have known, that users of these Pain Pumps, including Plaintiff Neil Strong, would not realize the dangerous condition of these Pain Pumps and their component parts.

97. As a direct and proximate result, Plaintiff has suffered and will continue to suffer injuries, damages, and losses as alleged herein.

COUNT II – STRICT PRODUCT LIABILITY – FAILURE TO WARN

98. Plaintiff incorporates by reference the preceding allegations as if fully set forth herein.

99. Defendants placed into the stream of commerce, and promoted for orthopedic and/or joint space use, Pain Pumps that were defective and in an unreasonably dangerous condition such that the foreseeable risks, including the risk of permanent destruction of the shoulder joint, exceeded the benefits associated with the design and/or formulation of the Pain Pump.

100. The Pain Pumps used after Neil Strong's surgeries were defective, unreasonably dangerous, and unsafe in that, among other things:

(a) When Defendants knew or should have known of the risk of injury to shoulder joint cartilage from their Pain Pumps, Defendants failed to use reasonable care to provide adequate warnings and instructions on their Pain Pumps concerning the risks presented by (i) using a higher dosage of pain medication, (ii) inserted into the surgical site, and (iii) for an extended period of time (namely, the risk of chondrolysis);

(b) When Defendants knew or should have known of the risk of injury to shoulder joint cartilage from their Pain Pumps, Defendants nevertheless continued to promote the Pain Pumps as safe and effective for use in orthopedic surgery in or near the joint space;

(c) The Pain Pump's instructions and labeling failed to instruct or warn Plaintiff Neil Strong, his surgeons, or the United States medical community at large that the safety of these Pain Pumps and the anesthetic solutions used in them had not been established for use in or near the joint space;

(d) The instructions and labeling failed to disclose to Plaintiff Neil Strong, his surgeons, or the United States medical community at large that continuous injection of commonly used anesthetics, such as those utilized in these Pain Pumps, for 48 hours or more, into or near the joint space, is very likely to cause serious and permanent injury to the joint, namely, chondrolysis;

(e) The instructions and labeling failed to include a precaution against placing the catheter of these Pain Pumps in or near the joint space;

(f) The instructions and labeling failed to provide to Plaintiff Neil Strong, his surgeon, or the United States medical community at large adequate instructions and warnings for any safe use of these Pain Pumps in or near the shoulder joint space;

(g) The instructions and labeling failed to disclose to Plaintiff Neil Strong, his surgeons, or the United States medical community at large that the FDA had specifically considered a request to permit use of pain pumps and catheters in the shoulder joint space, and the FDA had specifically rejected this request, on multiple occasions. Despite this specific, repeated denial of permission to market for such uses by the FDA, the Defendants nonetheless marketed, sold, and/or distributed these Pain Pumps specifically to be used directly in the shoulder joint space; and

(h) The defects in these Pain Pumps made these products unreasonably dangerous.

101. Defendants' failure to provide adequate warnings to Plaintiff, his surgeons, and the United States medical community at large caused Plaintiff's injuries.

102. As a direct and proximate result, Plaintiff has suffered and will continue to suffer injuries, damages, and losses as alleged herein.

COUNT III – NEGLIGENCE

103. Plaintiff incorporates by reference the preceding allegations as if fully set forth herein.

104. At all relevant times, the Defendants knew, or in the exercise of reasonable care should have known, that if the Pain Pump was not properly designed, manufactured, inspected, tested, packaged, labeled, distributed, marketed, and/or if the Defendants did

not provide proper warnings, the Pain Pump was likely to cause serious bodily injury to Plaintiff Neil Strong.

105. At all relevant times, Defendants had a duty to exercise reasonable care, and to comply with the existing standards of care, in their preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion, and sale of the Pain Pump, which Defendants introduced into the stream of commerce, including a duty to ensure that users would not suffer from unreasonable, dangerous or untoward adverse side effects, such as complete destruction of the shoulder joint cartilage.

106. The Defendants failed to exercise reasonable care in the design, manufacture, testing, inspection, packaging, labeling, distribution, and/or marketing of the Pain Pump and in providing adequate warnings. The Defendants' negligence includes, but is not limited to, the following:

(a) The Defendants negligently designed the Pain Pump and knew or had reason to know that the Pain Pump was likely to be dangerous for the use for which it was intended, supplied, marketed and promoted, *i.e.*, orthopedic use and/or use in or near the joint space;

(b) The Defendants failed to conduct a proper assessment and analysis of the design and assembly of the Pain Pump or its individual parts;

(c) The Defendants failed to properly test and/or inspect the Pain Pump in the environment in which it was to be used to confirm that the Pain Pump could be safely used in or near the joint space;

(d) The Defendants knew, or in the exercise of reasonable care should have known, about the risks that the Pain Pump presented, and specifically the risk of joint damage that could result from increased dosages of post-surgical anesthetic solutions administered for an extended period of time, and the Defendants nonetheless failed to exercise reasonable care to provide adequate pre- and post-market warnings and instructions to Plaintiff Neil Strong, his surgeon, and other medical providers using these Pain Pumps;

(e) The Defendants knew, or in the exercise of reasonable care should have known, that use of Pain Pumps with post-surgical anesthetic solutions in a joint space had not been approved and had in fact been specifically rejected by the FDA, and the Defendants nonetheless failed to advise Plaintiff Neil Strong, his surgeon, and other medical providers using Defendants' products of this fact;

(f) The Defendants knew, or in the exercise of reasonable care should have known, that a continuous injection of post-surgical anesthetic solutions directly into or near the joint, for 48 hours or more, had not been adequately tested for safety or effectiveness, and the Defendants nonetheless failed to advise Plaintiff Neil Strong, his surgeon, and other medical providers using Defendants' products of this fact; and

(g) The Defendants knew, or in the exercise of reasonable care should have known, that the risk of shoulder joint injury associated with using these Pain Pumps directly in or near the joint space outweighed any possible benefits of such use, such that the risk of inflicting on patients, such as Plaintiff Neil Strong, the permanent and disabling injury of chondrolysis was unreasonable in light of the foreseeability of this risk.

107. The Defendants' negligence in the design, formulation, manufacture, inspection, failure to test, packaging, labeling, warning, distribution, and marketing of the Pain Pump was a direct and proximate cause of Plaintiff Neil Strong's injuries and damages.

108. As a direct and proximate result of the Defendants' negligence, Plaintiff has suffered and will continue to suffer injuries, damages, and losses as alleged herein.

COUNT IV – FRAUD

109. Plaintiff incorporates by reference the preceding allegations as if fully set forth herein.

110. Defendants' agents and sales representatives knowingly, intentionally, directly and/or impliedly made material misrepresentations to Plaintiff's physicians and to the public that Pain Pumps were safe for use in the shoulder joint space.

111. The representations by Defendants' agents and sales representatives were in fact false, as Pain Pumps are not safe for human use in the shoulder joint space, but can cause permanent damage to the shoulder joint.

112. Defendants knew these representations were false, in that, among other things:

(a) Defendants did not know that joint space use of Pain Pumps was safe because Defendants had performed no safety testing for this use;

(b) Defendants knew that their Pain Pumps were not FDA-approved for use in the shoulder joint space because Defendants failed to provide the FDA with sufficient safety data;

(c) Defendants knew that the anesthetics used in their Pain Pumps had not been approved for use in the joint space; and

(d) Defendants' Pain Pumps were, in fact, not safe for use in the shoulder joint and could have an adverse effect upon Plaintiff Neil Strong's health when used in this manner.

113. That Pain Pumps were not safe for us in the shoulder joint was knowable, in that Defendant would have known that such use was unsafe had Defendants performed any safety testing.

114. When Defendants' agents and sales representatives made these representations that their Pain Pumps were safe for use in the shoulder joint space, Defendants knew those representations were false, deceptive, and misleading, and they made or allowed to be made those false representations with the intent to defraud, deceive, and mislead.

115. The misrepresentations and false information communicated by Defendants for the use of Plaintiff Neil Strong, his surgeons, and other medical providers using Defendants' products were material, and Plaintiff Neil Strong's surgeons, Dr. Farjo and Dr. Telfer, reasonably relied in good faith on Defendants' misrepresentations and false information, thus choosing to place the Pain Pump catheters in Plaintiff's shoulder joint, all to Plaintiff Neil Strong's detriment.

116. Plaintiff's physicians justifiably relied upon the misrepresentations of Defendants' agents and representatives and reasonably believed the misrepresentations to be true, and in justifiable reliance upon these misrepresentations, were induced to prescribe and use the Pain Pumps in the shoulder joint space.

117. Defendants are directly liable for the fraudulent conduct of its actual and/or ostensible employees, servants, and agents, including, but not limited to, its sales representatives. The fraudulent conduct of these employees, servants, and actual and/or ostensible agents, jointly and severally, caused and/or increased the risk of harm of, and the grievous injuries and damages sustained by Plaintiff.

118. As a direct and proximate result of Defendants' fraud, Plaintiff has suffered and will continue to suffer injuries, damages, and losses as alleged herein.

COUNT V – NEGLIGENT MISREPRESENTATION

119. Plaintiff incorporates by reference the preceding allegations as if fully set forth herein.

120. In the course of selling their Pain Pumps for commercial gain, Defendants had a duty to use reasonable care in conveying information about their Pain Pumps to Plaintiff, his surgeons, and other medical providers using Defendants' Pain Pump.

121. Defendants and their agents and sales representatives, in the course of their businesses, breached this duty by negligently misrepresenting and communicating to Plaintiff Neil Strong's surgeons, Dr. Farjo and Dr. Telfer, expecting and intending them to rely on the misrepresentations in advising their patients, false information upon which Plaintiff Neil Strong's surgeons and other medical providers using Defendants' products

relied for guidance in their decision to use the Pain Pump following Plaintiff Neil Strong's shoulder surgery.

122. The false information supplied by Defendants for the use of Plaintiff Neil Strong's surgeons and other medical providers using Defendants' products was that Defendants' Pain Pumps were safe, effective, and would not harm or adversely affect Plaintiff Neil Strong's health when used in orthopedic surgery and/or in or near the shoulder joint.

123. In making such representations, Defendants knew or should have known that the representations were false and not completely accurate at the time Defendants made the representations, as described above.

124. In making such representations, Defendants failed to exercise reasonable care in conveying truthful and accurate information for the use of Plaintiff Neil Strong, his surgeons, and other medical providers using Defendants' products.

125. The misrepresentations and false information communicated by Defendants for the use of Plaintiff Neil Strong, his surgeons, and other medical providers using Defendants' products were material, and Plaintiff Neil Strong's surgeons and other medical providers using Defendants' products reasonably relied in good faith on Defendants' misrepresentations and false information, all to Plaintiff Neil Strong's detriment.

126. The misrepresentations and false information were, at a minimum, negligent.

127. As a direct and proximate result of the negligent misrepresentations by Defendants and their agents and sales representatives, Plaintiff has suffered and will continue to suffer injuries, damages, and losses as alleged herein.

COUNT VI – BREACH OF EXPRESS WARRANTY

128. Plaintiff incorporates by reference the preceding allegations as if fully set forth herein.

129. On information and belief, the Defendants, through their agents, representatives, written literature, and advertisements expressly warranted to Plaintiff Neil Strong's surgeons that the Pain Pump was appropriate for use in or near the shoulder joint.

130. Plaintiff Neil Strong's surgeons reasonably relied on those warranties in choosing to use the Defendants' Pain Pumps in or near Plaintiff Neil Strong's shoulder joint.

131. The Pain Pumps designed, manufactured, inspected, packaged, labeled, distributed and/or marketed by the Defendants did not conform to the Defendants' representations because use of the Pain Pumps in or near the shoulder joint is unreasonably dangerous, in that such use can and did cause destruction of Plaintiff Neil Strong's articular cartilage.

132. The Defendants should have reasonably expected Plaintiff Neil Strong to use or be affected by the Pain Pumps.

133. As a direct and proximate result of the failure of the Pain Pumps designed, manufactured, inspected, packaged, labeled, distributed and/or marketed by the

Defendants to conform to the Defendants' representations regarding the safety of the Pain Pumps for use in or near the shoulder joint, Plaintiff has suffered and will continue to suffer injuries, damages, and losses as alleged herein.

COUNT VII – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

134. Plaintiff incorporates by reference the preceding allegations as if fully set forth herein.

135. At the time of their placement into the stream of commerce and at the time of the aforesaid injuries to Plaintiff Neil Strong, these Pain Pumps, together with instructions, warnings, labels, and materials explaining the selection and use thereof, were not fit for the ordinary purposes for which such products are intended and were unmerchantable to users and consumers, including Plaintiff Neil Strong, in that:

(a) Plaintiff Neil Strong's surgeons used the Pain Pumps in a manner for which Defendants intended and marketed the Pain Pumps to be used, that is, use in the shoulder joint;

(b) Defendants' Pain Pumps were unmerchantable for such use because use of Defendants' Pain Pumps in Plaintiff Neil Strong's shoulder joint can and did cause chondrolysis.

136. As a direct and proximate result of the Defendants' breaches of their implied warranties of merchantability, Plaintiff has suffered and will continue to suffer injuries, damages, and losses as alleged herein.

COUNT VIII – BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

137. Plaintiff incorporates by reference the preceding allegations as if fully set forth herein.

138. At the time of their placement into the stream of commerce and at the time of the aforesaid injuries to Plaintiff Neil Strong, Defendants impliedly warranted that the Pain Pumps were fit for pain management following surgery in the shoulder joint space.

139. The Pain Pumps were not fit for pain management following surgery in the shoulder joint space.

140. Defendants knew or should have known that Plaintiff's surgeons were relying on Defendants' skill or judgment in selecting the Pain Pump for post-operative pain management following should joint surgery.

141. Use of the Pain Pump in or near the joint space can and did result in permanent damage to Plaintiff Neil Strong's shoulder joint.

142. As a direct and proximate result of the Defendants' breaches of their implied warranties of fitness for a particular purpose, Plaintiff has suffered and will continue to suffer injuries, damages, and losses as alleged herein.

DAMAGES

143. Plaintiff incorporates by reference the preceding allegations as if fully set forth herein.

144. As a result of the acts and omissions of the Defendants set forth generally above, and other and further acts and omissions of a similar nature, Plaintiff Neil Strong has suffered and will suffer the following damages:

(a) Past expenses for medical, surgical, nursing, and rehabilitative care, therapy, and equipment;

(b) Future expenses for medical, surgical, nursing, and rehabilitative care, therapy, and equipment;

(c) Past and future lost wages and impairment of earning capacity;

(d) Past and future loss of household services;

(e) Past and future care gratuitously rendered;

(f) General damages for severe and excruciating pain, suffering, mental and emotional distress, permanent disability, substantial alterations of lifestyle, loss of enjoyment of life, scarring, and other significant damages; and

(g) Plaintiff's costs of this action, together with interest on special and general damages from the date of occurrence at the legal rate until paid, interest on any judgment awarded herein at the legal rate until paid, and other and further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendant as follows:

1. Economic and non-economic damages and damages for pain and suffering and loss of basic and pleasurable activities in an amount in excess of $75,000 as provided by law and to be supported by the evidence at trial;

2. For compensatory and other damages according to proof;

3. For disgorgement of profits;

4. For an award of attorneys' fees and costs;

5. For prejudgment interest and the costs of suit; and

6. For such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff requests that this case be tried by a jury.

Dated: June 10, 2010

LOCKRIDGE GRINDAL NAUEN P.L.L.P.

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